REMARKS

This submission is in response to the Office Action, dated June 7, 2007, a response to which is due on September 7, 2007. As this response is submitted within the three month shortened statutory period for reply, no fee is due. In view of claims cancellations, no additional claims fees are believed due.

Favorable consideration is respectfully requested in view of the foregoing Amendments and following Remarks.

I. STATUS OF THE CLAIMS:

Claim 1 has been amended to incorporate limitations from claim 3 which has been canceled. Claims 4 and 6 have been amended to change dependency from canceled claim 3 to claim 1. Claims 7 and 8 have been canceled. Claim 12 has been amended to correctly recite in the alternative. Claim 20 has been amended to incorporate limitations from claim 21 which has been canceled.

New claims 46-50 have been added. Claim 46 finds support in original claim 3. Claim 47 finds support in the Specification on page 10, line 14 and page 12, lines 1-8. Claims 48 and 49 find support in the Specification on page 9, line 17 and page 29, lines 14-16. Claim 50 finds support in original claim 21. Claim 51 finds support in the Specification on page 10, line 14 and page 12, lines 1-8. It should be self-evident that these new claims are part of elected Group I.

Applicants hereby cancel claims 25-45, the subject matter of the claims of Groups II and III, directed to a process of use and a process of making, from examination without prejudice, and expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application.

Accordingly, upon entry of this amendment, claims 1, 2, 4–6, 9–20, 22–24, and 46–51 are pending and under examination. No new matter has been introduced by way of these amendments.

II. RESTRICTION REQUIREMENT:

In the Office Action, the Examiner required restriction between the following three groups of claims:

- I. claims 1-24, directed to a product, classified in class 436, subclass 178;
- II. claims 25-39, directed to a process of use, classified in class 210, subclass 635.

III. claims 40-45, directed to a process of making, classified in class 210, subclass 506.

The Examiner stated that the inventions are distinct from each other because of the following reasons:

Inventions I and II are related as product and process of use. Citing MPEP § 806.05(h), the Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. The Examiner alleged that the product as claimed can be used in a materially different process such as chromatography.

Inventions I and III are related as product and process of making. Citing the Manual of Patent Examining Procedure ("MPEP") § 806.05(f), the Examiner stated that the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. The Examiner alleged that the process as claimed can be used to make materially different products, such as osmotic distillation membranes, or membranes for artificial lungs, plasma separation or water purification.

Inventions II and III are directed to process of use and process of making. Citing MPEP § 806.05(j), the Examiner stated that the inventions can be shown to be distinct if one of the following can be shown: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; or (3) the inventions as claimed are not obvious variants. The Examiner alleges that the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, or effect. The Examiner further alleges that the inventions as claimed do not encompass overlapping subject matter, and there is nothing of record showing them to be obvious variants, and further that the making of product and process of use of product perform distinct functions as claimed such as chromatography, osmotic distillation membranes, and use in artificial lungs.

In a telephone interview with Bella Fishman on May 8, 2007, a provisional election of Group I, claims 1–24, was elected with traverse. Applicants hereby elects Group I without traverse and cancels claims 25–45, the subject matter of the claims of Groups II and III, directed to a process of use and a process of making, from examination without prejudice,

and expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application.

Accordingly, upon entry of this amendment, claims 1, 2, 4-6, 9-20, 22-24, and 46-51 are pending. No new matter has been introduced by way of these amendments.

III. REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1-5, 7-11, 13-19, and 24 stand rejected under 35 U.S.C. § 102(b) as anticipated by PCT Application WO 02/088672 to Varian, Inc. (hereinafter, "Varian, Inc.").

Regarding claim 1, the Examiner alleges that Varian, Inc. discloses a hollow fiber comprising a liquid extraction membrane made from synthetic organic polymers and a hollow fiber which "encloses an internal cavity separated from a donor sample by the extraction membrane placing a static acceptor liquid in the internal cavity" (page 2, lines 31–33 to page 2, lines 1–5 and page 6, lines 2–3).

In response, Applicants have amended claim 1 to more particularly point out and distinctly claim that which Applicants regard as their invention. Claim 1 as amended now incorporates limitations from claim 3, and in particular, now recites constituents for the liquid membrane. (See further discussion with regard to grounds for claim 3 rejection below.) Accordingly, Applicants respectfully submit that claim 1 as amended is not anticipated by Varian, Inc. and request that the rejection be withdrawn.

As for claim 2, the Examiner alleges that Varian, Inc. discloses that the polymeric substrate is a hollow fiber membrane (page 2, line 6 and page 6, lines 2-3). In response, Applicants point out that page 6, lines 2-3 make no mention of hollow fibers. Other references to hollow fibers exist in Varian, Inc., but none disclose liquid membranes as recited by amended claim 1, from which claim 2 depends. Accordingly, Applicants respectfully submit that claim 2 is not anticipated by Varian, Inc. and request that the rejection be withdrawn.

As for claim 3, the Examiner alleges that Varian, Inc. discloses that the membrane comprises supports made of cellulose, which is a fatty acid ester (page 6, lines 28–30) and a coating of a polyester which is interpreted as a fatty acid ester (page 22, line 6). Applicants respectfully traverse. First of all, the Examiner errs in interpreting both cellulose and polyester as "fatty acid esters." A "fatty acid ester" is defined in the specification (page 10, lines 15–18): "typically comprises an acyl chain comprising from 12 to 20 carbon atoms, and an ester portion comprising from 1 to 12 carbon atoms," and may be "saturated, unsaturated,"

linear, or branched, and may also include halogenated analogues." Applicants respectfully point out that fatty acid esters do not encompass cellulose (a polymer of glucose, a sugar) or polyester (a synthetic polymer of ester monomers). Secondly, Varian, Inc. discloses cellulose as a support, not as a constituent of the liquid membrane. Accordingly, Varian, Inc. does not disclose a membrane comprising supports made from fatty acid esters as the Examiner contends. Applicants respectfully submit that original claim 3 and amended claim 1 are not anticipated by Varian, Inc. and request that the rejection be withdrawn.

As for claims 4 and 5, the Examiner alleges that Varian, Inc. discloses the membrane coating as a polyester (page 22, lines 3-6) which can have 12-30 carbon atoms in the acyl chain and 1-12 atoms in the ester portion as this is a polymer and able to have many carbon atoms in the chain or ester group. Applicants respectfully traverse. While Varian, Inc. does describe the use of coatings formed from polymeric materials, as noted above, a polyester is still not a fatty acid ester. The fact that an acyl chain comprises multiple carbon atoms does not render it a polymer, or a polyester in particular. Further, the polymeric coatings do not appear to qualify as liquid membranes, as used herein (See Specification, page 8, lines 1-6, and page 9, line 27 – page 11, line 9). Therefore, Varian, Inc. does not disclose or suggest the subject matter of claims 4 and 5. Accordingly, Applicants respectfully submit that the rejection has been overcome and request that the rejection be withdrawn.

As for claims 7 and 8, the Examiner alleges that Varian, Inc. discloses a membrane which is an aryl alkyl ether containing the polar nitro functionality (page 34, lines 25–26) where the alkyl portion of the ether can have 5–30 carbon atoms and the aryl portion of the ether can have 5–20 carbon atoms. In response, claims 7 and 8 have been canceled.

As for claim 9, the Examiner alleges that Varian, Inc. discloses membrane fibers able to "carry" the acceptor solution on the lumen side (page 9, line 33 and page 10 lines 1–2). Applicants respectfully traverse. The Examiner cites prior art which uses the term "carry" in an entirely different sense from the "carrier" described by Applicants (Specification, page 11, lines 11–32). The Examiner's rejection is non-sensical in the context of carriers which "can provide selectivity to particular analytes" and which typically are organic ions including ionophores and pore forming agents, as defined in the instant Specification. Therefore, Varian, Inc. does not teach each and every element of the pending claims. Accordingly, Applicants respectfully submit that the rejection has been overcome and request that the rejection be withdrawn.

As for claims 10 and 11, the Examiner alleges that Varian, Inc. discloses carrier fibers made of different polymeric materials such as polypropylene, polysulfone, polycarbonate or polyether sulfone which are able to isolate a single analyte from a complex mixture or group of analytes (page 10, lines 13-18). The Examiner further alleges that the fibers "having an ability of separating a single analyte from a mixture or group is characterized as an ionophore, transporting specific ions through a cellular membrane, and an organic ion." The rejection appears to be non-sensical in the same way as the rejection of claim 9, in that the Examiner has misconstrued the meaning of "carrier" as well as the term "ionophore." Varian, Inc. does not mention the term carriers, ionophores, organic ions, or pore-forming agents for the purpose of providing selectivity for any analytes, nor are these constituents inherent in any of the membranes or coatings described by Varian, Inc. Rather, Varian, Inc. points to the "fiber chemistry," specifically the polymeric materials used to form the fibers, as possibly conferring some selectivity for analytes. However, fiber "chemistry" does not encompass, disclose or suggest the use of carriers such as ionophores, organic ions and pore-forming agents. As such, Varian, Inc. does not teach each and every element of the pending claims. Accordingly, Applicants respectfully submit that the rejection has been overcome and request that the rejection be withdrawn.

As for claim 13, the Examiner alleges that Varian, Inc. discloses that the fibrous polymeric membrane can be made from polyesters, polyurethanes and functionalized polyolefins (page 8, line 33 and page 10, line 1). However, Varian, Inc. makes no mention of a liquid membrane comprising the constituents as claimed in amended claim 1, and so does not teach each and every element of the pending claims. As claim 13 depends from amended claim 1, Applicants respectfully submit that this rejection has been overcome and request that the rejection be withdrawn.

As for claim 14, the Examiner alleges that Varian, Inc. discloses that the membrane can be made of polyolefins (page 10, line 1). However, Varian, Inc. makes no mention of a liquid membrane comprising the constituents as claimed in amended claim 1, and so does not teach each and every element of the pending claims. As claim 14 depends from amended claim 1 (via claim 13), Applicants respectfully submit that this rejection has been overcome and request that the rejection be withdrawn.

As for claim 15, the Examiner alleges that Varian, Inc. discloses that the fibers in the membrane can be made of polypropylene, polysulfone, polycarbonate or polyether sulfone, etc. (page 10, lines 16–18). Again, Varian, Inc. makes no mention of a liquid membrane

comprising the constituents as claimed in amended claim 1, and so does not teach each and every element of the pending claims. As claim 15 depends from amended claim 1 (via claims 13 and 14), Applicants respectfully submit that this rejection has been overcome and request that the rejection be withdrawn.

As for claim 18, the Examiner alleges that Varian, Inc. discloses that the aqueous feed solution is on the shell side of the fiber and the organic solvent acceptor solution is on the lumen side with the same solvent forming the supported membrane (page 12, lines 1-3). However, Varian, Inc. makes no mention of a liquid membrane comprising the constituents as claimed in amended claim 1, and so does not teach each and every element of the pending claims. As claim 18 depends from amended claim 1, Applicants respectfully submit that this rejection has been overcome and request that the rejection be withdrawn.

As for claim 19, the Examiner alleges that Varian, Inc. discloses that the liquid membrane hollow fiber can be employed in well plate and autosample formats in a static mode that can furnish a high degree of sample enrichment (page 11, lines 30-32). However, Varian, Inc. makes no mention of a liquid membrane comprising the constituents as claimed in amended claim 1, and so does not teach each and every element of the pending claims. As claim 19 depends from amended claim 1, Applicants respectfully submit that this rejection has been overcome and request that the rejection be withdrawn.

Applicants have thus addressed each and every rejection under 35 U.S.C. § 102(b) and requests that these rejections be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Varian, Inc. as applied to claim 3 and further in view of U.S. Patent No. 3,612,283 to Stricker (hereinafter, "Stricker"). The Examiner alleges that Varian, Inc. discloses the claimed invention except for compositions of the membrane comprising vegetable oil, specifically soya oil, olive oil, or tea tree oil. The Examiner alleges that Stricker teaches that membranes impregnated with olive oil are known (column 1, lines 51-54), and that this type of membrane does not permit passage of substances of an acid character if present in weakly acid to neutral solutions. The Examiner alleges that it would have been obvious to construct the liquid membrane of olive oil to provide a hydrophobic layer on the membrane "as to not be solvated or degraded by the solvent."

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Applicants respectfully traverse. While Stricker discloses that cellulose membranes impregnated with olive oil are known (by reference to the work of Levy et al, J. Pharm. Sci. 57(2), 235-239 (1968)), this disclosure is in the context of filter membranes used in an attempt to model in vitro the intestinal absorption of pharmaceutical agents, an entirely different application not adapted for the requirements of performing liquid phase microextraction (LPME). Stricker does not disclose or suggest the use of olive oil in LPME. There is no teaching, suggestion, or motivation to be found in either Varian, Inc. or Stricker to use olive oil for the purpose of providing long-lived liquid membranes for LPME. The Examiner's allegation that "it would have been obvious to construct the liquid membrane of olive oil to provide a hydrophobic layer on the membrane 'as to not be solvated or degraded by the solvent' " is simply erroneous in that there is no solvent involved, and no such teaching is present, implied or suggested by Stricker or Varian, Inc. A person of ordinary skill in the art at the time the invention was made would have had no motivation to combine these references and would not have combined the teaching of these references to obtain the invention of claim 6.

Furthermore, it would not even have been "obvious to try" olive oil as a constituent of a liquid membrane for LPME, were that an allowable standard for obviousness. Stricker does mention the use of olive oil in filter membranes known in the art, but mentions olive oil only to discuss its unsuitability for use in an in vitro resorption model of the gastrointestinal tract. Further, Stricker teaches away from the use of olive oil by specifically citing limitations to the use of these membranes for analytical purposes, stating that membranes impregnated with olive oil "do not permit the passage of substances of an acid character if they are present in weakly acid to neutral solutions" and "are not well suited" to his application. Such comments would lead one skilled in the art away from the claimed invention, and thus teach away from the pending claims.

In addition, the present Applicants have unexpectedly discovered that stable liquid membranes can be prepared that exhibit unexpectedly long-term stability and usability and that can be utilized successfully in LPME after extended periods of time, issues which are not addressed, predicted or suggested in any way by Varian, Inc. or Stricker, alone or in combination. Thus, the presently claimed invention demonstrates superior and unexpected results relative to the prior art references cited by the Examiner. Previous work described in Varian, Inc. or Stricker provides no guidance toward the claimed invention or for achieving the superior results disclosed in the instant Specification and Examples.

Accordingly, Applicants respectfully submit that the rejection has been overcome, and request that the rejection be withdrawn.

Claims 16 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Varian, Inc. The Examiner alleges that Varian, Inc. discloses that hollow fiber membranes can have a lifetime of five days or less, and that a membrane made of nitrophenyloctyl ether can have a lifetime of between 10 and 20 days. The Examiner alleges that in would have been obvious to construct the membrane to last 30, 60, or 90 days, since it has been held that discovering an optimum value of a variable involves only routine skill in the art (citing In re Boesch, 617.F.2d 272, 205 USPQ 215 (CCPA 1980)).

Applicant respectfully traverses. First of all, claims 16 and 17 cannot be rendered obvious by Varian, Inc. at least because claim 1 as amended (from which these claims depend) does not encompass nitrophenyloctyl ether as a possible liquid membrane constituent.

Secondly, the standard of In re Boesch with regard to discovering an optimum value for a variable applies only to variables that a person of ordinary skill in the art can actually vary in routine experiments. The observed experimental results regarding duration of usability of liquid membranes represents output parameters from the experiments (what is observed) and not input variables (what is varied) that can be routinely adjusted. Achieving a particular experimental output or result can occasionally be obvious if prior art shows a known functional relationship between the output and input variables, but if, as in this case, no such known functional relationship exists, then the required experiments are not at all routine. See In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) and MPEP § 2144.05.II.B: "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." [Emphasis added]. The "particular parameter" in the present invention is the number of days for which the liquid membrane is stable. This parameter is not a "resulteffective variable," in that prior art has not achieved a recognized result in correlating the choice of liquid membrane materials with this variable, and more than routine experimentation is required to find materials which can be used to make liquid membranes with the claimed stability. Applicants thus respectfully submit that this rejection has been. overcome and should be withdrawn.

Claims 20-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Varian, Inc. in view of US Patent No. 6,354,443 to Moya (hereinafter, "Moya"). Regarding claim 20, the Examiner alleges that Varian, Inc. teaches the claimed invention except for a hollow fiber comprising a porous polymeric substrate and a liquid membrane. The Examiner alleges that Moya teaches construction of a porous membrane substrate made of a thin polymeric porous or ultrafiltration membrane formed of a polymeric composition (column 11, lines 11-14). The Examiner alleges that it would have been obvious to construct the membrane from a porous polymeric substrate as taught by Moya to isolate a particular analyte extracted from a large volume of sample solution.

Applicants respectfully traverse. Moya teaches a porous membrane whose surface is completely modified with a perfluorocarbon copolymer composition (see Abstract). This copolymer is a solid material (see the example compositions in columns 7-9) and cannot function as a liquid membrane for microextraction of analytes. Unlike the invention of claim 20, this solid-phase coating is not used or usable to selectively pass analytes. Rather, Moya teaches the use of perfluorocarbon copolymer coatings to provide a more hydrophilic surface than the underlying substrate to improve the wettability of filter membranes by aqueous solutions. Such a coating may improve the performance of mechanical filtration, but it provides no analyte separation capability by chemical composition and cannot function as a liquid membrane as required by the pending claims. Moya clearly teaches away from the invention of claim 20, which is based on a liquid membrane of a hydrophobic character that is capable of selectively passing analytes through the liquid layer itself and not through holes or pores in the polymeric support. Thus, the combined teachings of Varian, Inc. and Moya do not teach the invention of claim 20, and the rejection should be withdrawn. As claims 21-24 are dependent from claim 20, rejections of these claims should be withdrawn as well.

As for claim 21, the Examiner alleges that Varian, Inc. discloses a membrane comprising supports made of cellulose which is interpreted to be a fatty acid ester (page 7, lines 28-30) and also discloses a polyester coating which is interpreted as a fatty acid ester (page 22, line 6). The Examiner further alleges that Moya teaches construction of a porous membrane from a thin polymeric porous or ultrafiltration membrane substrate formed of a polymeric composition (column 11, lines 11-14), and that it would have been obvious to make the porous polymeric membrane from fatty acid esters to obtain a high enrichment of analyte in the hollow fiber from the donor solution.

Applicants respectfully traverse. As noted above in traversing the rejection of claim 3 under 35 U.S.C. §102(b), Applicants assert that the examiner has erred in construing a polyester coating as a fatty acid ester. Thus, the combined teachings of Varian, Inc. and Moya do not teach the invention of claim 21. For this reason, and because claim 21 depends from claim 20, which Applicants submit has been shown to be nonobvious over Varian, Inc. in view of Moya, Applicants submit that the rejection of claim 21 has been overcome and should be withdrawn. Claim 21 has, in any case, been canceled, and limitations therefrom have been incorporated into claim 20.

As for claim 22, the Examiner alleges that Varian, Inc. teaches that hollow fiber polymeric membranes can be formed by polymerization of monomers in the pores or by coating the preformed polymers, and that examples of polymers that can be used are polyesters, polyurethanes, and functionalized polyolefins (page 8, lines 30–33 and page 9, line 1). The Examiner further alleges that Moya teaches construction of polymer membranes of fluorine-containing polymers (column 11, lines 29–30), and that it would have been obvious to construct the membrane from polymers to obtain high separation efficiency for the analyte in the sample solution.

Applicants respectfully traverse this rejection. Applicants wish to point out that while claim 22 does recite possible polymeric substrates onto which the liquid membrane is formed, the fact that polymerization of monomers in pores is taught by Varian, Inc. is irrelevant to this claim. In addition, the Examiner's allegation that "it would have been obvious ... to construct the membrane from polymers to obtain a high separation efficiency for the analyte in the sample solution" is also irrelevant because the liquid membrane is not constructed from polymers, rather, a porous polymeric support serves as the support for the liquid membrane. The Examiner is invited to review the definition of the term "liquid membrane" in the Specification at page 8, first paragraph, and at page 9, line 28 – page 11, line 9. Thus, the combined teachings of Varian, Inc. and Moya do not teach the invention of claim 22. In addition, as claim 22 is dependent from amended claim 20, which Applicants submit to be nonobvious over Varian, Inc. in view of Moya, Applicants submit that the rejection of claim 22 has been overcome and should be withdrawn.

As for claim 23, the Examiner alleges that Varian, Inc. and Moya teach the claimed invention in that the polymeric substrate includes polyolefins such as polyethylene, polypropylene, and polymethylpentene (column 11, lines 25–31), and that "it would have been obvious ... to construct the membrane from polyolefins so that no exposed substrate

surface is present and the uniform construction promotes uniform filtration." Applicants respectfully submit that even if it were obvious to construct the membrane from polyolefins such that no exposed substrate surface is present or in a way that promotes uniform filtration, this combination of references is not relevant to pending claim 23 since the membrane is not constructed from polyolefins, rather, the polymeric substrate can comprise a polyolefin, while the membrane is formed from an organic phase formed onto the polymeric substrate, as described in the Specification. Thus, the combined teachings of Varian, Inc. and Moya do not teach the invention of claim 23. In addition, as claim 23 is dependent from amended claim 20, which Applicants submit to be nonobvious over Varian, Inc. in view of Moya, Applicants submit that the rejection of claim 23 has been overcome and should be withdrawn.

As for claim 24, the Examiner alleges that Varian, Inc. and Moya teach the claimed invention in that Varian, Inc. discloses that hollow fiber membranes can have a lifetime of five days or less and a membrane made of nitrophenyloctyl ether can have a lifetime of between 10 and 20 days. The Examiner alleges that in would have been obvious to construct the membrane to last 30, 60, or 90 days, since it has been held that discovering an optimum value of a variable involves only routine skill in the art (citing *In re Boesch*, 617.F.2d 272, 205 USPQ 215 (CCPA 1980)).

Applicants respectfully traverse for the reasons cited above regarding the rejection of claims 16 and 17 under 35 U.S.C. § 103(a). It cannot be obvious to construct the membrane to last 30, 60, or 90 days, since the number of days for which the liquid membrane is stable is not a "result-effective variable," in that prior art has not achieved a recognized result in correlating the choice of liquid membrane materials with this variable. Therefore, more than routine experimentation is required to find materials which can be used to make liquid membranes with the claimed stability. For this reason, and because claim 24 is dependent from claim 20, which Applicants submit to be nonobvious over Varian, Inc. in view of Moya, the rejection of claim 24 has been overcome and should be withdrawn.

V. REJECTION UNDER 35 U.S.C. § 112

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner alleges that the claim language at the beginning states that the "organic ion is" and at the end of the claim, the language denotes "and." The Examiner stated that it is unclear if the organic ions are all of the ions listed or is one from the list. In response, claim

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12 has been amended to make the language definite and correctly recite the organic ions in the alternative by substituting the word "or" for "and."

CONCLUSION

Entry of this Amendment is respectfully requested. Favorable consideration is respectfully requested in view of the foregoing Amendments and Remarks.

If the Examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, she is welcome to contact the undersigned attorney at (650) 565-8185:

As this submission is timely submitted and no additional excess claims fees have been incurred, there are no fees due.

Respectfully submitted,

Dated: September 6, 2007

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